Remarks

This is a response to the Office Action mailed May 20, 2003. Presently, claims 1, 4, 8-10, 13-15, 18 and 22 are pending and have been rejected. Claims 1, 8, 9, and 13 have been amended. Claim 4 has been cancelled.

Rejection under 35 U.S.C. 103(a)

The Office Action states that claims 1, 4, 8-10, 13-15, 18 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,769,236 to Panoz *et al.* (the '236 patent) in view of the Physicians Desk Reference (the PDR).
The Office Action states that the '236 patent discloses spraying an amorphous form of an active ingredient in the presence of a stabilizer and a crystal forming inhibiting agent, wherein in one embodiment the inhibiting agent is constituted by the mixture of polyethylene glycol and polyvinylpyrrolidone. Further, the Examiner states that the PDR discloses that fenofibrate is a known active agent with success in regulating lipid content.

It is well established law that the PTO has the burden under 35 U.S.C. § 103 to establish a case of a *prima facie* obviousness. To satisfy this burden, an Examiner must identify both (i) a suggestion to modify a primary reference in accordance with the teachings of one or more secondary references to achieve the claimed invention and (ii) a reasonable expectation of success in making and using the modified procedure (In re Vaeck, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991)).

Moreover, an Examiner may not use an applicant's disclosure as a guide or template to select elements from prior art references which, when combined together arrive at the claimed invention (In re Fritch, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992)).

Applicants respectfully submit that this rejection under 35 U.S.C. § 103 is in error because the combination of references does not present a *prima facie* case of obviousness of the claimed invention.

The present invention as amended claims a pharmaceutical composition comprising a solid dispersion of fenofibrate and hydroxypropylmethylcellulose (HPMC) as a crystallization inhibitor in a polyethylene glycol (PEG) carrier. Moreover, the present invention claims the step of making said solid dispersion, and a method of

treating hyperlipidemia with the solid dispersion, which is the subject matter of the repent invention.

The '236 patent claims a process of preparing a pharmaceutical composition of an active ingredient using polyvinylpirrolidone and any polyalkyleneglycol. The PDR simply describes the applications of fenofibrate to treat hyperlipidemia.

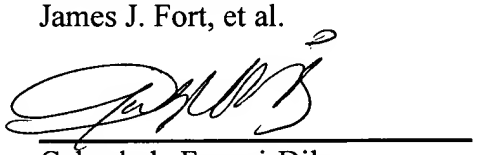
Applicants respectfully submit that a suggestion to modify the '236 patent in accordance with the teachings of the PDR, or *vice versa,* to achieve the claimed invention, has not been identified in the Office Action. Additionally, facts implying that there is a reasonable expectation of success in using the teachings of the PDR or the '236 patent in making and using the present invention have not presented in the Office Action.

The '236 patent discloses and claims polyvinylpirrolidone as the agent that retards crystallization, and also discloses and claims a process to improve the solubility of a medicament, a process that is totally different to the process described in the present application. The final composition in the '236 patent is a solution that is then atomized in order to obtain a stable amorphous active principle-PVP composition, in which the active principle is never fenofibrate, as substantiated in Examples 1, 2, and 3-25. The process of making the composition of the '236 patent does not provide a reasonable expectation of success in making the present invention. The Office Action states that Applicants are substituting a new active ingredient in a known process. The process described in the '236 patent pertains to the active ingredient and the inhibiting polymer being dissolved in a solvent, and then atomized in a sprayer. Applicants emphasize that the present application describes and claims a process in which the active ingredient is added to a PEG: inhibiting HPMC mix in an organic solvent, the solution is then dried to obtain a composition that is a solid dispersion made of an active principle-HPMC-PEG, which can be subsequently conformed to a tablet or a capsule.

Conclusions

In view of the facts and arguments discussed above, Applicants respectfully submit that the claims in the present application are patentable over the prior art and request allowance of the same.

Respectfully submitted,
James J. Fort, et al.



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